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TITLE: A Novel Urinary Catheter with Tailorable Bactericidal Behavior

PRINCIPAL INVESTIGATOR: Dr. Hassan Razvi

CONTRACTING ORGANIZATION: LONDON HEALTH SCIENCES CENTRE RESEARCH
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6. AUTHOR(S)
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5d. PROJECT NUMBER

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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This is a project being conducted at two sites. Our US collaborator's role is the development of novel biomaterials that will be used to manufacture urinary catheters. Our portion of the project is the evaluation of these urinary catheters first in vitro, and then in an in vivo animal model. We have established animal protocols and written ethics in place to be able to undertake this work once we receive the materials from our research collaborator.

15. SUBJECT TERMS
None listed

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**		7	**19b. TELEPHONE NUMBER** *(include area code)*
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1. **INTRODUCTION:**

Catheter-associated urinary tract infections (CAUTIs) are the most common nosocomial infection globally accounting for roughly 40% of all reported healthcare-associated infections (HAIs). Developing more biocompatible and infection-resistant urinary catheter materials may help to reduce the morbidity and mortality associated with CAUTIs. We believe that the proposed research has the potential to significantly reduce costs (product and care) and improve outcomes for military and civilian populations. In this project there are six specific aims that will be evaluated to test the silicone composite materials that employ a novel antimicrobial ion exchange (AM-IE) resin system. Four of the aims are (*in vitro*) to be carried out at Iasis Molecular Sciences and are intended to optimize device configurations. Two specific aims to be carried out by ourselves (Razvi & Burton) are intended to evaluate the *in vivo* performance of these devices in a rabbit model.

2. **KEYWORDS:**
CAUTI, urinary tract infection, catheter, infection, silicone

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

Our contribution to the project is to test the novel polymers that have been developed using in vitro and in vivo evaluations. At this time we are awaiting delivery of he materials in order to begin our portion of the study. (Aims 4-8).

Specific Aim 1 – To synthesize coating polymers, identify an optimal lubricious coating, and optimize antiseptic loading
Specific Aim 2: Synthesis of AM-IE resins, fabrication, and testing of ten composite silicone test articles
Specific Aim 3: In Vitro characterization of six AM-IE silicone composites with antiseptic lubricious coating
_____OUR AIMS START HERE_____
Specific Aim 4: Determination of *in vitro* efficacy of the candidate composites
Specific Aim 5: *In vivo* rabbit ureteral stent model
Specific Aim 6: *In vivo* rabbit urethral catheter model
Specific Aim 7: Histopathological evaluation of kidney, bladder and ureter tissue samples
Specific Aim 8: Reporting and results evaluation for future clinical evaluations
_____

- **What was accomplished under these goals?**

We have derived animal protocols and ethics for our in vivo studies.

- **What opportunities for training and professional development has the project provided?**

NA

- **How were the results disseminated to communities of interest?**

Nothing to report.

- **What do you plan to do during the next reporting period to accomplish the goals?**

Our part of the project will be well underway by this time next year. We anticipate we will have completed our in vitro studies, and the animal studies will be underway.

4. **IMPACT**
   - **What was the impact on the development of the principal discipline(s) of the project?**

Nothing to Report.

- **What was the impact on other disciplines?**

Nothing to Report.

- **What was the impact on technology transfer?**

Nothing to Report.

- **What was the impact on society beyond science and technology?**

Nothing to Report.

5. **CHANGES/PROBLEMS:**
   - **Changes in approach and reasons for change**
   - **Actual or anticipated problems or delays and actions or plans to resolve them**
   - **Changes that had a significant impact on expenditures**
   - **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
   - **Significant changes in use or care of human subjects**
   - **Significant changes in use or care of vertebrate animals.**
   - **Significant changes in use of biohazards and/or select agents**

Nothing to Report.

6. **PRODUCTS**
    - *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*
        - **Publications, conference papers, and presentations**
        - **Journal publications.**
        - **Books or other non-periodical, one-time publications.**
        - **Other publications, conference papers, and presentations.**

Nothing to Report.

- **Website(s) or other Internet site(s)**
- **Technologies or techniques**
- **Inventions, patent applications, and/or licenses**
- **Other Products**

Nothing to Report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	*Patricia Rosas Arellano*
Project Role:	*Coordinator*
Researcher Identifier (e.g. ORCID ID):	*NA*
Nearest person month worked:	*3*
Contribution to Project:	*Dr Arellano has coordinated documents and protocols*
Funding Support:	*This award*

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to Report.

- **What other organizations were involved as partners?**

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

Nothing to Report.

9. APPENDICES

Nothing to Report.